

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on October 31, 2008. The Office Action provided a three-month shortened statutory period in which to respond, ending on January 31, 2009. Accordingly, this amendment is timely submitted. No fees are believed due with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-929 on the account statement.

Claims 1, 5-8, 10-11 and 26-27 are pending in this application. Claims 2-4, 9 and 12-25 were previously canceled without prejudice or disclaimer. In the Office Action, Claim 10 is objected to. Claims 1, 5-8, 10-11 and 26-27 are rejected under 35 U.S.C. §112. Claims 1, 5-8, 10-11 and 26-27 are rejected under 35 U.S.C. §103. Applicants do not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicants reserve the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

In response, Claims 1, 10 and 27 have been amended and Claim 5 has been canceled without prejudice or disclaimer. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claim 10 is objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Patent Office asserts that Claim 1 requires fiber in the amount of about 25 g, Claim 5 requires about 20 g or 15 g, but Claim 10 teaches that the composition contains 2.5, which is “nowhere near the about 25, 20 or 15 g in the previous claims.” See, Office Action, page 2, lines 9-15. In response, Applicants note that Claim 1 has been amended to recite, in part, that the composition requires from about 15 g to about 20 g of the oligosaccharide blend, Claim 5 has been canceled without prejudice or disclaimer and Claim 10 has been amended to delete reference to FOS and GOS in the composition. The amendments do not add new matter. The amendments are supported in the

specification at, for example, page 8, lines 31-34. For at least the above-mentioned reasons, Applicants respectfully submit that the objection to Claim 10 is now rendered moot.

Accordingly, Applicants respectfully request that the objection to Claim 10 be reconsidered and withdrawn.

In the Office Action, Claims 1, 5-8, 10-11 and 26-27 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Patent Office alleges that "nowhere in the instant specification is a daily dosage of 25 g disclosed." See, Office Action, page 3, lines 1-11. Applicants note that currently amended Claim 1 no longer requires a daily dosage of 25 g. For at least the above-mentioned reasons, Applicants respectfully submit that the rejection of Claims 1, 5-8, 10-11 and 26-27 for requiring a daily dosage of 25 g is now rendered moot.

Further, the Patent Office also alleges that newly added Claim 27 contains the transition phrase "consisting essentially of" and that nowhere in the instant specification is there disclosed a composition which is only FOS and GOS since "all of the instant examples contain other components such as glutamine or proteins, fats, etc. (Examples 1-4)." The Patent Office further rejects Claims 1, 5-8, 10-11 and 26-27 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because the Patent Office alleges that the specification "does not reasonably provide enablement for about 25, about 20 or about 15" g of an oligosaccharide blend. See, Office Action, page 3, lines 11-18.

In response, and with respect to the rejection of Claim 27, Applicants initially note that the specification explicitly states at page 10, lines 4-5 that, in an embodiment, "the compositions of the invention consist essentially of, or exclusively of, FOS and GOS as described herein." As such, Applicants respectfully submit that, while the transition phrase "consisting essentially of" need not be explicitly found in the specification to be used in pending claims, in the instant case, the exact language that the Patent Office states is not supported in the specification is used, word for word, in the specification. Further, Applicants also note that compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on

predicted results rather than work actually conducted or results actually achieved. An applicant need not have actually reduced the invention to practice prior to filing. See, MPEP 2164.02. Therefore, Applicants respectfully submit that, even if the Patent Office is correct that there are no working examples that describe the use of from about 15 g to about 20 g of an oligosaccharide blend, such a requirement is not necessary and the present disclosure is still enabling.

With respect to Claims 1, 5-8, 10-11 and 26-27, and the Patent Office's allegation that the specification "does not reasonably provide enablement for about 25, about 20 or about 15" g of an oligosaccharide blend, Applicants note that an analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

Indeed, the Patent Office relies on the eight factors from *In re Wands* to assert that Claims 1, 5-8, 10-11 and 26-27 are allegedly not enabled. However, Applicants respectfully disagree with the Patent Office's analysis. For example, with respect to the breadth of the claims, the Patent Office asserts that the only scope supported by the specification would include "2 g (Example 2), 9.86 g (Example 3), and 2.5 g (Example 4) of fiber (FOS and GOS) in a single composition." See, Office Action, page 5, lines 1-2. Regarding the amount of direction provided by the inventor, the Patent Office asserts that "[t]here is nothing in the specification that would indicate that the current invention is capable of working at any amount higher than 10g (or the 9.86 g of Example 3)." See, Office Action, page 6, lines 4-6. With respect to the presence or absence of working examples, the Patent Office states that "[t]here are no examples provided of any amount above 10g, and certainly not 25g, 20g or 15g and as such these amounts are not supported." See, Office Action, page 6, lines 16-17.

However, contrary to the Patent Office's assertion, and as discussed above, the present claims are, in fact, supported by the specification, regardless of whether the scope of the claims is set out in an example. As discussed above, compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed. Indeed, the presence of a working example is just one of at least eight factors to consider when evaluating enablement. Further, an example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. An applicant need not have actually reduced the invention to practice prior to filing. See, MPEP 2164.02. Therefore, Applicants respectfully submit that, even if the Patent Office is correct that there are no working examples that describe the use of from about 15 g to about 20 g of an oligosaccharide blend, the present disclosure is still enabling.

With respect to the state of the prior art, the Patent Office alleges that "[t]he art teaches that a single composition should not contain more than 10 g of fiber and Applicant instant Examples do not contain more than 10g of fiber." The Patent Office also states that "[i]t is clear from the prior art above that amounts in a single composition above 10g give discomfort to a person." See, Office Action, page 5, lines 16-22. However, Applicants respectfully submit that the Patent Office mischaracterizes the scope of the prior art.

For example, the present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, the present invention has shown that the prebiotic properties of FOS are significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (*i.e.*, a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type

of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention.

Finally, with respect to the quantity of experimentation, the Patent Office continues to assert that “a burdensome amount of research would be required by one of ordinary skill in the art to bridge [the] gap” between a composition comprising 2g, 2.5g, and 9.86g and a composition comprising about 25g, about 20g or about 15g of fiber. See, Office Action, page 6, line 19-page 7, line 1. However, Applicants respectfully disagree. Instead, Applicants note that specific amounts of specific ingredients for use in the present compositions are clearly set forth in the specification. Among those specific amounts of ingredients, a composition comprising from about 15 g to about 20g of fiber is clearly set forth in the specification. According, since the Patent Office admits that the relative skill of those in the art is very high (e.g., Ph.D and M.D. level technology), Applicants respectfully submit that the skilled artisan would be more than capable of measuring from about 15 g to about 20 g of fiber to include in a composition comprising both FOS and GOS in the presently claimed ratios. Indeed, the relative skill of a Ph.D or an M.D. is not even required to be able to create a composition according to the present claims that include from about 15 g to about 20 g of fiber. For at least these noted reasons, Applicants respectfully submit that the present claims are fully enabled by the specification and would not require a burdensome amount of experimentation for the skilled artisan to obtain compositions according to the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 5-8, 10-11 and 26-27 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

In the Office Action, Claim 5 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Patent Office asserts that Claim 5 recites the broad limitation “of about 20g” and “15g,” which is narrower than the 20g. See, Office Action, page 8, lines 6-8. In response, Applicants note that Claim 5 has been canceled without prejudice or disclaimer. In view of the cancellation of Claim 5, Applicants respectfully submit that the rejection of Claim 5 under 35 U.S.C. §112, second paragraph is now rendered moot.

Accordingly, Applicants respectfully request that the rejection of Claim 5 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

In the Office Action, Claims 1, 5-8, 10-11 and 27 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,399,124 to Lesens et al. ("*Lesens*"). However, Applicants respectfully submit that *Lesens* is deficient with respect to the present claims.

Currently amended independent Claim 1 recites, in part, a composition comprising an oligosaccharide blend comprising FOS and GOS, the composition comprising from about 15 g to about 20 g of the oligosaccharide blend, a weight ratio of FOS and GOS being from about 0.5 to about 20 and the FOS and GOS being capable of synergistically promoting the growth of *Lactobacilli*. Currently amended independent Claim 27 recites, in part, a composition comprising an oligosaccharide blend consisting essentially of FOS and GOS, wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 8, lines 31-34.

As discussed above, the present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, the present invention has shown that the prebiotic properties of FOS are significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (*i.e.*, a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention. In contrast, Applicants respectfully submit that *Lesens* fails to disclose each and every limitation of the present claims.

Lesens fails to disclose or suggest compositions having an oligosaccharide blend comprising FOS and GOS, the composition comprising about from about 15 g to about 20 g of the oligosaccharide blend, a weight ratio of FOS and GOS being from about 0.5 to about 20 and the FOS and GOS being capable of synergistically promoting the growth of *Lactobacilli*, or compositions having an oligosaccharide blend consisting essentially of FOS and GOS, a weight ratio of FOS and GOS being from about 0.5 to about 20 and the FOS and GOS being capable of synergistically promoting the growth of *Lactobacilli* as is required, in part, by Claims 1 and 27, respectively. Instead, *Lesens* is directed to frozen desserts that contain lactic acid bacteria and dietary fibers and its benefit to the human health after consumption of the frozen desserts. The maximum amount of fibers that make up the edible support of the frozen desserts is 10 g of fiber per dessert. According to *Lesens*, higher quantities of fibers would induce an unpleasant feeling of heaviness in the stomach. See, *Lesens*, col. 5, lines 23-29. As such, the highest amount of fiber that may be attained by the frozen desserts of *Lesens* is about 10 g. This is in direct contrast to the present invention, which currently claims from about 15 g to about 20 g of the oligosaccharide blend of FOS and GOS. Further, *Lesens* also fails to disclose or suggest compositions having an oligosaccharide blend consisting essentially of FOS and GOS, as required, in part, by currently amended independent Claim 27. Indeed, the Patent Office even admits that *Lesens* fails to disclose a composition having the specific amounts of the present claims. See, Office Action, page 11, lines 13-14.

Instead, the Patent Office asserts that it would have been obvious to one of ordinary skill in the art to make a composition of FOS and GOS in a specific ratio. As support for this statement, the Patent Office asserts that "Examples 4-5 of *Lessens* et al teach a cone made of Raftilose L30 (table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). Such a ratio would yield a weight ratio of 1.56 FOS:GOS in the single food composition." See, Office Action, page 10, lines 8-12. The Patent Office cites other portion of *Lesens* as disclosing other claimed elements of the present invention. However, Applicants respectfully submit that the rejections are based on a misunderstanding of the disclosure of *Lesens*.

For example, the Examples cited by the Patent Office as disclosing the use of either FOS or GOS do not even use the FOS and GOS in the same compositions, let alone the FOS and GOS used in the same compositions as an oligosaccharide blend. At best, *Lesens* discloses that an aerated ice creams may be dipped into compositions having GOS (Table 3) or FOS (Table 4), or that ice cream may be contained in a wafer dough containing FOS (Examples 4-5) or GOS (Example 5). At no place in the disclosure does *Lesens* disclose the use of FOS and GOS in an oligosaccharide blend. In fact, *Lesens* never discloses that the FOS and GOS are used in the same composition, let alone as an oligosaccharide blend of a specific amount, or as an oligosaccharide blend consisting essentially of those two oligosaccharides as required, in part, by the present claims.

Moreover, it appears that the Patent Office maintains the previous rejections based, at least in part, on the merits of the present rejections under 35 U.S.C. §112. Specifically, the Patent Office alleges that “Applicant’s instant specification does not teach how to make [and] use a formulation above 10g of fiber” and that “the addition of new claim 27 with the language ‘consisting essentially of’ does not overcome the prior art of record and is treated as ‘comprising’ since Applicant does not provide evidence that additional components would materially change the characteristics of the instant invention.” See, Office Action, page 17, lines 3-7 and 13-16. As the merits of these assertions are discussed at length above, Applicants do not reiterate the arguments here. However, Applicants respectfully submit that since the rejections under 35 U.S.C. §112 have now been overcome in view of the arguments contained herein, and that the §112 rejections are not relevant to the rejections of any of the claims under 35 U.S.C. §103.

Moreover, *Lesens* teaches away from the present claims. As discussed above, *Lesens* discloses that “the dessert may be designed so as to be able to potentially provide up to a maximum of 10 g of fibre per dessert, high quantities of fibers indeed inducing an unpleasant feeling of heaviness in the stomach.” See, *Lesens*, col. 5, lines 23-26 (emphasis added). This is in direct contrast to the present claims, which require, in part, from about 15 g to about 20 g of an oligosaccharide blend of FOS and GOS. The Patent Office asserts that “[t]he amount of fiber claimed in *Lesens et al* (claim 9) is not outside the scope of the instant claim 10 which claims

only 2.5% fiber; therefore there is no teaching away only an 'upper limit' placed on the fiber amount." See, Office Action, page 19, lines 15-21. However, Applicants respectfully disagree with the Patent Office's analysis.

First and foremost, Applicants note that Claim 10 has been amended to deleted amounts of FOS and/or GOS. Second, Applicants respectfully submit that the presence of an "upper limit" in *Lesens* requires that *Lesens* prohibits the use of any more than the "upper limit." As such, Applicants disagree with the Patent Office's assertion that such an upper limit would not teach the skilled artisan away from the use of fibers that are greater than the upper limit. For at least the above-mentioned reasons, Applicants respectfully submit that *Lesens* fails to disclose each and every element of the present claims.

In the Office Action, Claims 1, 5, 7-8, 10-11 and 27 are rejected under 35 U.S.C. §103(a) as being unpatentable over J. Pediatric Gastroenterology and Nutrition, volume 34, pages 291-295 to Moro et al. ("*Moro*") and Arch. Dis. Child Fetal Neonatal. Ed., Volume 86, pages F178-F181, 2002 to Boehm et al. ("*Boehm*") and *Pediatrics*, Vol. 21, Nov/Dec, pages 39-48, 2001 to Rigo et al. ("*Rigo*"), all in view of *Lesens*. Applicants respectfully submit that the cited references are deficient with respect to the present claims.

As discussed above, independent Claim 1 recites, in part, a composition comprising an oligosaccharide blend comprising FOS and GOS, the composition comprising from about 15 g to about 20 g of the oligosaccharide blend and a weight ratio of FOS and GOS from about 0.5 to about 20; and independent Claim 27 recites, in part, a composition comprising an oligosaccharide blend consisting essentially of FOS and GOS and a weight ratio of FOS and GOS from about 0.5 to about 20. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Moro, *Boehm* and *Rigo* all fail to remedy the deficiencies of *Lesens*, discussed at length above. Specifically, *Moro*, *Boehm* and *Rigo* all fail to disclose or suggest compositions capable of synergistically promoting the growth of *Lactobacilli*, the compositions comprising an oligosaccharide blend comprising FOS and GOS, from about 15 g to about 20 g of the oligosaccharide blend and a weight ratio of FOS and GOS from about 0.5 to about 20; or

compositions capable of synergistically promoting the growth of *Lactobacilli*, the compositions comprising an oligosaccharide blend consisting essentially of FOS and GOS and a weight ratio of FOS and GOS from about 0.5 to about 20 as required, in part, by independent Claims 1 and 27, respectively. As previously discussed, *Moro* and *Boehm* share three common authors, disclosed similar findings and were published around the same period by the same scientific institution. Both *Moro* and *Boehm* studied the bifidogenic effects of an oligosaccharide mixture on faecal flora and stool characteristics of preterm infants. To do this, an oligosaccharide mixture consisting of 90% GOS and 10% FOS was supplemented into a standard pre-term infant formula at a concentration of 10 g/L. The object of combining the oligosaccharide mixture and the pre-term infant formula by *Moro* and *Boehm* is to “mimic the molecular size distribution of human milk oligosaccharides” and to “benefit from a possible synergistic effect of both [FOS and GOS] compounds to stimulate the growth of *Bifidobacteria*.” See, *Moro*, page 292. While *Moro*, *Boehm* and *Rigo* aimed to mimic the contents of breast milk, *Lesens*, on the other hand, intended the frozen dessert composition to promote the growth of beneficial gastrointestinal bacteria.

Further, *Moro* reported results that showed no statistical difference between the group of infants fed a formula with 0.4 g/dL oligosaccharides and the group of infants fed a formula with 0.8 g/dL oligosaccharides. See, *Moro*, Abstract. Similarly, with respect to *Boehm*, the results obtained indicated that “*Lactobacilli* were also detectable in all infants at the study entry. There was a significant increase in all groups during the course of the study period but there was no significant effect on the diet (data not shown). Neither was there a significant effect on the oligosaccharide supplement on the counts of *Bacteroides*, *Clostridium* species, *E. coli*, *Enterobacter*, *Citrobacter*, *Proteus*, *Klebsiella*, and *Candida*. See, *Boehm*, page F180, left column, third full paragraph.

In *Rigo*, the growth and quality of growth of term infants fed with a New Formula (NF) were similar to those seen in infants that were fed with breast fed and conventional formulas. The composition of the NF includes prebiotic substances such as FOS and GOS wherein the total amount together is 0.4 g/100ml; partially hydrolyzed whey protein and β -palmitate. According to *Rigo*, the “use of prebiotic substances in NF resulted in a rapid and significant increase in the

percentage of endogenous bifidobacteria and the ability to maintain a stable intestinal flora during the first months of age.” See, *Rigo*, page 39.

Further, the Patent Office asserts that *Moro* and *Boehm* disclose an oligosaccharide mixture of 90% GOS and 10% FOS and that “[t]his satisfies the weight ratio of FOS:GOS of about 0.5 to about 20. However, it is unclear to Applicants how a composition having a ratio of FOS:GOS of 1:9 can disclose a weight ratio of FOS:GOS of about 0.5 to about 20. For at least the above-mentioned reasons, Applicants respectfully submit that *Moro*, *Boehm*, *Rigo* and *Lesens* all fail to disclose each and every element of the present claims.

In the Office Action, Claims 1 and 26-27 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Lesens* in view of U.S. Publ. No. 2003/0138476 to Van Leeuwen et al. (“*Van Leeuwen*”). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

As discussed above, independent Claim 1 recites, in part, a composition comprising an oligosaccharide blend comprising FOS and GOS, the composition comprising from about 15 g to about 20 g of the oligosaccharide blend and a weight ratio of FOS and GOS from about 0.5 to about 20. Independent Claim 27 recites, in part, a composition comprising an oligosaccharide blend consisting essentially of FOS and GOS and a weight ratio of FOS and GOS from about 0.5 to about 20. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Because *Lesens* fails to disclose a composition including glutamine, the Patent Office cites *Van Leeuwen* solely for the disclosure of composition including glutamine and prebiotics. However, *Van Leeuwen* fails to remedy the deficiencies of *Lesens*, discussed at length above. Specifically, *Van Leeuwen* fails to disclose or suggest compositions capable of synergistically promoting the growth of *Lactobacilli*, the compositions comprising an oligosaccharide blend comprising FOS and GOS, from about 15 g to about 20 g of the oligosaccharide blend and a weight ratio of FOS and GOS from about 0.5 to about 20; or compositions capable of synergistically promoting the growth of *Lactobacilli*, the compositions comprising an oligosaccharide blend consisting essentially of FOS and GOS and a weight ratio of FOS and

GOS from about 0.5 to about 20 as required, in part, by independent Claims 1 and 27, respectively.

Van Leeuwen is entirely directed toward the “use of glutamic acid for the preparation of a nutritional preparation that is intended for use for the treatment or prevention of excess or undesired permeability of the intestinal wall. See, *Van Leeuwen*, Abstract. The nutritional preparation can be “combined with suitable prebiotics and probiotics, which have a beneficial effect on the intestinal flora. The prebiotics comprise short or long chain oligosaccharides, in particular galacto-oligosaccharides and fructo-oligosaccharides . . .” See, *Van Leeuwen*, page 2, [0017]. However, *Van Leeuwen*, similar to *Lesens*, fails to disclose compositions comprising an oligosaccharide blend comprising FOS and GOS, from about 15 g to about 20 g of the oligosaccharide blend and a weight ratio of FOS and GOS from about 0.5 to about 20; or compositions capable of synergistically promoting the growth of *Lactobacilli*, the compositions comprising an oligosaccharide blend consisting essentially of FOS and GOS and a weight ratio of FOS and GOS from about 0.5 to about 20 as required, in part, by independent Claims 1 and 27, respectively.

Moreover, Applicants respectfully submit that there exists no reason to combine *Van Leeuwen* and *Lesens* to obtain the present claims because *Van Leeuwen* teaches away from *Lesens*. Each reference must be considered as a whole and those portions teaching against or away from each other and/or the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994)..

For example, while *Lesens* is entirely directed toward compositions having lactic acid bacteria for the purpose of treatment and/or prevention of gastrointestinal disorders, for strengthening the human immune system and for increasing the absorption of minerals, see, *Lesens*, Abstract, *Van Leeuwen* is entirely directed toward the use of glutamic acid for the

treatment or prevention of excess or undesired permeability of the intestinal wall, see, *Van Leeuwen*, Abstract. Applicants respectfully submit that simply because both references refer to prebiotics including, for example, FOS and GOS, the simple mention of the prebiotics by both references fails to provide a reason to combine the cited references. Therefore, the skilled artisan would have no reason to combine the cited references.

In response to the Patent Office's assertion that Applicants have addressed the references individually and not as a combination of references, Applicants respectfully submit that, to the extent that the references are discussed individually, it is not to address the rejections as anticipation rejections, but rather to point out the deficiencies of the cited references. In this case, not only would the skilled artisan lack any reason to combine the cited references, but the cited references also fail to disclose each and every element of the present claims.

Accordingly, Applicants respectfully request that the obviousness rejections of Claims 1, 5-8, 10-11 and 26-27 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Patent Office is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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